UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/092,637	03/07/2002	Lester David Michels	30895B/C1	1332

1095 7590 11/10/2003

THOMAS HOXIE
NOVARTIS, CORPORATE INTELLECTUAL PROPERTY
ONE HEALTH PLAZA 430/2
EAST HANOVER, NJ 07936-1080

EXAMINER	
MADSEN, ROBERT A	
ART UNIT	PAPER NUMBER
1761	

DATE MAILED: 11/10/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/092,637	MICHELS ET AL.	
	Examin r	Art Unit	
	Robert Madsen	1761	

-- The MAILING DATE of this communication appears on th cov r she t with the correspond nce address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-15 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-15 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Aoi et al. (US 565895) in view of Gans et al. (US 4025650) and Furia

3. Regarding claims 1-9,11,12,Aoi et al. teach enteral complete solutions (i.e. administered in 1500-2000 kcal per day, which is a conventional diet kcal consumption) to prevent nutritional deficiency of cancer patients. The solution is combined with a feeding tube system, as recited in claim 11, has a pH of 3-8, 2-6.9 or greater than 5.5 as recited in claims 2-4, which may include esters of p-hydroxybenzoic acid (i.e. parabens), salts of benzoic acid, and salts of sorbic acid as recited in claim 1(Abstract, Column 3, lines 1-21, Column 4, lines 34-53,Column 5, lines 23-30, Column 6, lines 23-35). Aoi et al. however are silent in teaching the particular type or amount of parabens, salts of benzoic acid, and salts of sorbic acid, as recited in claims, 1,5-9, and 12.

4. Gans et al. also teach compositions that prevent nutritional deficiency. Gans et al. are relied on as evidence of using one or more preservatives from 0.4-1% such as potassium sorbate, sodium benzoate methyl paraben and propyl paraben, alone or in combination in a nutritional formula, as recited in claims 5,7, 9(Abstract, Column 3, lines

22-35, Column 4, line 20 to Column 5, line15). Gans et al. are also relied on evidence of the conventional dose of the preservatives. Gans et al. teach 0.12% of potassium sorbate and sodium benzoate, as well as 0.05% propyl paraben and 0.12% methyl paraben as recited in claims 1 and 8 (See Table 1, which teaches 0.4% preservatives, in light of the 15.5 lbs of total preservatives in Example 1).

5. Furia is relied on as further evidence of the conventionality of the particular effective amount of each paraben, the cumulative effect of adding both benzoates and parabens, and the use of ethyl paraben, as recited in claim 6, in certain countries (Page 126 and 127 See Regulatory Use and Applications, Page 124 Table 3).

6. Therefore, it would have been obvious to modify Aoi et al. and include either 0.1-0.2% methyl paraben or 0.05-1.0% propyl paraben, 0.1-0.2% sodium benzoate and 0.1-0.2% potassium sorbate, as recited in claims 1,5,7-9,12 since Aoi et al. teach preservatives include parabens and salts of both sorbic acid and benzoic acid and Gans et al. teach these are appropriate forms of paraben and acid salts, as well as appropriate quantities for a nutritional solution. One would have been substituting one preservative for another for a nutritional solution.

7. To include ethyl paraben, as recited in claim 6, would have been an obvious result effective variable of the particular regulatory status of the area in which the enteral solution is used, since Furia teach ethyl paraben is approved in some countries, while not approved in others.

8. Regarding claim 10, Aoi et al. teach xanthan gum and carageenan are suitable stabilizers for the solution (Column 4, lines 48-50), but Aoi et al. are silent in teaching a

particular quantity. Aoi et al. teach the solution is for use in combination with a feed tube, and it is notoriously well known in the art that xanthan gum and carageenan contribute to a solution's viscosity. Therefore, to select any particular quantity of xanthan gum and carageenan would have been an obvious result effective variable of the desired solution viscosity since the greater the viscosity of the enteral solution the less easily it would flow through a feed tube.

9. Claims 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gans et al. (US 4025650) in view of Aoi et al. (US 565895).

10. Regarding claims 13-15, Gans et al. teach a method of preserving nutrient diet solutions, which would thus include inhibiting the growth of any bacteria or mold. Gans et al. teach adding 0.12% of both potassium sorbate and sodium benzoate, as well as 0.05% propyl paraben and 0.12% methyl paraben to *preserve* the composition, in an acidic pH, that is less than 7, which is included in the range recited in claim 15 (See Table 1, which teaches 0.4% preservatives, in light of the 15.5 lbs of total preservatives in Example 1, Column 3, lines 22-35, Column 4, line 20 to Column 5, line15). Gans et al. do not teach inhibiting bacterial growth in a *complete solution.*

11. Aoi et al. teach a method of stabilizing enteral complete solutions (i.e. administered in 1500-2000 kcal per day, which is a conventional diet kcal consumption), with a pH of 3-8 as recited in claim 15, using esters of p-hydroxybenzoic acid (i.e. parabens), salts of benzoic acid, and salts of sorbic acid (Abstract, Column 3, lines 1-21, Column 4, lines 34-53,Column 5, lines 23-30, Column 6, lines 23-35).

Therefore, once it was known to preserve (i.e. inhibit the growth of any bacteria or mold) a given liquid nutrient solution with 0.12% potassium sorbate, 0.12% sodium benzoate, and 0.12% methyl paraben, to preserve any type of nutrient solution, such as a *complete solution*, would have been an obvious matter of choice, depending on the intended use of the solution, since Aoi et al. teach it is known to stabilize complete enteral solutions with parabens and salts of both sorbic acid and benzoic acid .

Conclusion

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Goldstein et al. (US 6143037) teach coating medical devices with parabens, sorbic acid, and benzoic acid from 0.1 to 1% to prevent contamination.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Madsen whose telephone number is (703)305-0068. The examiner can normally be reached on 7:00AM-3:30PM M-F.

14. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Milton Cano can be reached on (703)308-3959. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

15. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist at (703) 308-0061.

Robert Madsen
Examiner
Art Unit 1761

MILTON I. CANO
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1700